REMARKS

In the Office Action dated November 3, 2003, claims 6-20 are pending in the present application. Claims 11-17 and 19-20 are withdrawn from further consideration as drawn to a non-elected invention. The Examiner has objected to Applicants' priority claim. Claims 6-10 and 18 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Guastella (U.S. 5,789,201, 1998). Claims 6-10 and 18 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Claims 6-10 and 18 are rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enabling support.

This Response addresses each of the Examiner's rejections. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

The Examiner alleges that the Applicants have not complied with the conditions for receiving the benefit of an earlier filing date under 35 U.S.C. §§119 and 120. Specifically, the Examiner points out that the Preliminary amendment, filed on August 9, 2002, modified the nucleotide sequences of SEQ ID NO: 6 and SEQ ID NO: 8 and Figure 9A and 9B of the instant application. The Examiner alleges that these modifications are not supported by the priority documents: Serial No. 09/155,327 (the parent case) and AU PN8965 (filed on March 27, 1996). The Examiner alleges that the Applicants failed to point out the specific disclosure in the foreign priority document AU PN8965 that supports the changes made in the instant application. Therefore, the Examiner concludes that the instant application is only entitled to a priority date of August 9, 2001, which is the filing date of the present application.

By way of the instant response and in an effort to favorably advance the prosecution of the present application, Applicants respectfully withdraw the previously filed substitute

drawing sheets of Figures 9A and 9B. Accordingly, the objection to the drawings is obviated. Withdrawal of the objection is respectfully requested.

As to the sequences, Applicants respectfully submit herewith a substitute Sequence Listing to replace the Sequence Listing of record. The attached substitute Sequence Listing is identical to the Sequence Listing filed with the Preliminary Amendment on August 9, 2002, with the exception that SEQ ID NO: 6 and SEQ ID NO: 8 in the attached Sequence Listing are identical to those as disclosed in the instant application when originally filed in the United States under 35 U.S.C. §371 on March 29, 1999.

In view of the foregoing, the objection to the priority claim is overcome. Withdrawal of the objection is therefore respectfully requested.

Claims 6-10 and 18 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Guastella (U.S. 5,789,201, 1998).

Claim 6 is drawn to an isolated polypeptide having 47% or greater similarity to amino acid sequences as set forth in SEQ ID NO: 7 or SEQ ID NO: 9; a polypeptide encoded by a nucleotide sequence as set forth in SEQ ID NO: 6 or SEQ ID NO: 8 or having 47% or greater similarity thereto; or a polypeptide encoded by a nucleic acid capable of hybridizing to the nucleotide sequence as set forth in SEQ ID NO: 6 or SEQ ID NO: 8 under low stringency conditions and encoding an amino acid sequence having 47% or greater similarity to SEQ ID NO: 7 or 9.

According to the Examiner, the '201 patent teaches a nucleotide sequence encoding a bcl-2-homolog (bcl-y), which matches 98.2% to SEQ ID NO: 6 and 95.9% to SEQ ID NO: 8. The '201 patent further allegedly teaches an amino acid sequence which matches 99.5% to SEQ ID NO: 7 and 99.3% to SEQ ID NO: 9.

Applicants observe that the '201 patent issued on August 4, 1998, i.e., after the filing date of both AU PN8965 (March 27, 1996) and PCT/AU97/00199 (March 27, 1997), from both of which the present application claims priority. Applicants also observe that the underlying application of the '201 patent was filed on February 11, 1997 and claims the benefit of Provisional Application 60/012,201, filed February 23, 1996. Thus, Applicants respectfully submit that the '201 patent is not a proper reference under 35 U.S.C. §102(b) as the Examiner has alleged. Withdrawal of the rejection under 35 U.S.C. §102(b) based on the '201 patent is therefore respectfully requested.

Claims 6-10 and 18 rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement.

The Examiner contends that the specification only teaches human and mouse bcl-w proteins comprising the amino acid sequence of SEQ ID NO: 7 (encoded by SEQ ID NO:6) or SEQ ID NO: 9 (encoded by SEQ ID NO: 6), respectively. The specification allegedly does not disclose any variant of human or mouse bcl-w explicitly or implicitly that has the bcl-w like activity. The Examiner also alleges that the specification does not disclose any distinguishing information about the claimed amino acid sequences, such as the relevant structural or physical characteristics. In addition, the Examiner contends that 53% variation (47% identity) would certainly affect proper folding and biological activity if amino acids that are critical for such functions are substituted, since the relationship between the sequence of a polypeptide and its tertiary structure is nether well understood nor predictable. In the Examiner's opinion, one skilled in the art would conclude that the Applicants were not in possession of the claimed genus at the time the application as filed.

Applicants respectfully submit that the law does not require a reduction to practice for the purpose of satisfying the written description requirement under 35 U.S.C. §112, first paragraph. Furthermore, Applicants respectfully submit that the specification describes the sequences (i.e., the structure) and the biological function of two polypeptides that are representative of the claimed polypeptide genus. Therefore, it is respectfully submitted that the claimed polypeptides are adequately described in compliance with the written description requirement. Withdrawal of the rejection under the written description requirement of 35 U.S.C. §112 is therefore respectfully requested.

Claims 6-10 and 18 are rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enabling support. The Examiner contends that the specification is enabling for isolated polypeptides comprising the amino acid sequence of SEQ ID NO: 7 (encoded by SEQ ID NO: 6) or SEQ ID NO: 9 (encoded by SEQ ID NO: 6), but not for any variant or derivative of these specific polypeptides.

According to the Examiner, the Bcl-2 family comprises various members that have very diverse functions. The Examiner contends that it is highly unpredictable that the variants as claimed (encompassing 53% sequence variations) would have any bcl-2-like activity, and that those skilled in the art would have to engage in extensive making and testing in order to obtain variants that have bcl-2 and/or bcl-w like-activity. In addition, the Examiner contends that it would also require undue experimentation for those skilled in the art to use the variants in pharmaceuticals compositions, as claimed, for treating diseases.

Applicants respectfully submit that the present specification provides adequate guidance that enables those skilled in the art to make and use the claimed polypeptides. For example, the specification teaches the isolation of the human bcl-w gene (SEQ ID NO: 6), the

murine bcl-w gene (SEQ ID NO: 8), and the encoded polypeptides. The specification also shows that the human Bcl-w protein and the murine Bcl-w share about 90% similarity. Moreover, the specification provides specific exemplification demonstrating that Bcl-w enhances cell survival. See pages 35-36 of the specification. In light of the present teaching, those skilled in the art can isolate a nucleic acid molecule that either hybridizes to SEQ ID NO: 6 or 8, or encodes a protein that shares at least about 47% similarity to SEQ ID NO: 7 or 9, and determine whether the encoded protein enhances cell survival. It is respectfully submitted that the experimentation required for those skilled in the art to make and use the claimed polypeptide is not undue. Accordingly, the rejection under the enablement requirement of 35 U.S.C. §112, first paragraph is overcome. Withdrawal of the rejection is respectfully requested.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

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Encls.:
Substitute Paper and Substitute Computer-Readable Copies of Sequence Listing;
§1.821(f) Statement